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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,704	06/02/2000	Toyokazu Ishikawa	9150-0008.10	9123

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EXAMINER

BROWN, STACY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicant(s)

09/555,704

Applicant(s)

ISHIKAWA ET AL.

Examiner

Stacy S Brown

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7,9,10,13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,9,10,13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's response filed May 2, 2003 is acknowledged and entered. Claims 1-3, 5, 7, 9, 10, 13 and 15-18 are pending.
2. The rejection of claims 1, 9, 15, 17 and 18 under 35 U.S.C. 102(a) as being anticipated by Ding *et al* is withdrawn in view of Applicant's persuasive arguments. The rejection of claims 1-3, 5, 7, 9, 10, 13 and 15-18 under 35 U.S.C. 103(a) as obvious over Ding in view of Liao is withdrawn in view of Applicant's persuasive arguments.

### *Claim Rejections - 35 USC § 103*

3. The rejection of claims 1-3, 5, 7, 9, 10, 13 and 15-18 under 35 U.S.C. 103(a) as obvious over Huiying *et al* in view of Liao *et al* is maintained for reasons of record.

#### Applicant mainly argues that:

- None of the references alone or in combination teach the step of inactivation followed by a step of physical purification.

In response, Huiying teaches the purification of inactivated Japanese encephalitis particles. Huiying purifies the particles using zonal centrifugation and protamine sulfate and is silent on the method of inactivation. However, according to an English translation (provided by the PTO but not provided to Applicant) of the method steps of Huiying, the zonal centrifugation steps are followed by freeze-drying. This implies that the inactivation step occurred prior to the centrifugation step. Liao's method uses solely physical purification means. It would have been obvious to modify the method of Huiying with the purification process of Liao. One would have

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been motivated to purify Huiying's particles by physical means alone because Liao teaches that a method for purification is desired that does not impair native structures and biological activities (col. 2, lines 20-22). One would have known that Liao's method reduces the effects of chemical treatments on the particles. One would have had a reasonable expectation of success that the physical purification method of Liao would have worked in the method of Huiying because both are purifying JEV particles in large quantities from cell cultures.

- None of the references alone or in combination teach the claimed high neutralizing antibody titers in response to immunization with the inactivated virus particles produced.

In response, the combined methods of Huiying and Liao result in a method and product that is a functional equivalent of Applicant's particle and method of making. Since the product is made in the same manner as Applicant's, the product is expected to have the same properties as Applicant's. The same level of neutralizing antibody titers would be elicited from Huiying/Liao's method as Applicant's method.

### ***Conclusion***

4. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SJB

Stacy S. Brown  
June 25, 2003

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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6/30/03